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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,151	06/08/2005	Giovanni Mogna	HOFF-38315	3249
86378	7590	04/16/2009		
Pearne & Gordon LLP 1801 East 9th Street Suite 1200 Cleveland, OH 44114-3108			EXAMINER BADR, HAMID R	
			ART UNIT 1794	PAPER NUMBER
			NOTIFICATION DATE 04/16/2009	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/538,151	<b>Applicant(s)</b> MOGNA, GIOVANNI	
	<b>Examiner</b> HAMID R. BADR	<b>Art Unit</b> 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 16-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

Applicants' amendment filed on 12/19/2008 is acknowledged.

Claims 16-30 are being considered on the merits.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 16-24 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amended claim 16 is not supported, in the specification, for the cheese making steps in general, and claim 16 is not supported for "wherein before adding the starter culture to the milk, at least one strain of lactic bacteria..... is added to the milk" in specific. No statements can be found in the instant specification to support the presently amended claim 16.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 16-24 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16-24 and 27 are indefinite for the phrase "to improve coagulation". It is unclear what is meant by "to improve coagulation". It is unclear what the applicant regards as the

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invention. The term "improve" is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear over what standard this is to be "improved", and also what properties are "improved" (i.e. faster time, increased yield, etc.).

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 16-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 5,942,263; hereinafter R1) in view of Sandine et al. (US 4,205,132; hereinafter R2) and Yamauchi et al. (US 5,527,505; hereinafter R3).

3. R1 discloses a method for manufacturing cheese including pre-acidifying milk, ripening milk to yield cheese milk, coagulating the milk by adding a coagulant to yield a coagulum, cutting the coagulum, separating the curd from whey, salting, milling and molding the curds (Abstract).

4. R1 teaches adding the starter to the milk and incubating at 34C to reduce the pH to 6.25. (Col. 3, lines 57-59)

5. R1 teaches using *Lactobacillus lactis*. It also teaches using a blend of different starter cultures. Starter culture is typically added at 72 ml starter per 1000 lbs. of milk or 0.75% (wt/wt)

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(Col. 4, lines 7-14). Furthermore, the rate of culture addition at 0.01-1.0% of milk is normal in the art. R1 also discloses that a mixture of mesophilic and thermophilic starter cultures may be used (Col. 4, lines 9-11). Those skilled in the art know that the starter culture is added before coagulating the milk, and as such the improvement in milk coagulation will be inherent in cheese making processes where a starter culture is employed.

6. R1 teaches using a coagulant such as chymosin to produce cheese curd. Further details of the process are given by R1.

7. R1 is silent regarding the use of anhydrous form of starters, the number of bacteria added to the milk, or addition of starters to the raw (unpasteurized) milk.

8. R2 discloses the production of lyophilized starter cultures which are storage stable (Abstract).

9. R2 gives a number of lactic acid producing bacteria which may be included in the lyophilized preparation. (Col. 3, lines 29-39).

10. R2 teaches that the bacteria which are best adapted to the process of the invention are those which are used to produce lactic acid in milk for cheese making (Col. 4, lines 43-45).

11. R2 teaches that a liquid culture contains at least about  $10^8$  to  $10^{15}$  cells per ml. Given that about 15 ml starter culture is used for 220 pounds (100 liters) of milk (paragraph 9 above) and assuming a starter containing  $10^{10}$  cells per ml, the total number of cells added to the milk will be about  $1.5 \times 10^{11}$  cells per 100 liters.

12. R1 and R2 are silent regarding the addition of starter cultures to raw (unpasteurized) milk.

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13. R3 discloses a fermented milk with a controlled acidity increase during storage and transportation. The fermented milk can be manufactured by inoculating raw milk with *Lactococcus lactis* subsp. *Lactis* together with other lactic acid bacteria to be used for fermenting the raw milk (Abstract). Given that R3 teaches of adding *Lactococci* to raw milk, it is obvious that such a milk can further be processed to make cheese as presently claimed.

14. It would have been obvious to one of ordinary skill in the art at the time the invention was made, to modify the teachings of R1 and implement the teachings of R2 by using anhydrous (lyophilized) cultures and adopt the teachings of R3 to add the starter cultures to raw (unpasteurized) milk. One would do so to benefit from acidification of milk before coagulating the milk to make cheese which would affect the texture and/or organoleptic characteristics of the final product, and the acidified raw milk will also storage and transportation advantages. Absent any evidence to contrary and based on the combined teachings of the cited references there would be a reasonable expectation of success in acidifying the milk and coagulating it to make cheese.

### ***Response to arguments***

Applicants' arguments have been thoroughly reviewed. These arguments are not deemed persuasive for the following reasons.

1. The certificates of the deposition of the bacterial strains have been accepted. The enablement requirement of the 35 U.S.C. 112(1) has been met. The rejection under 35 U.S.C. 112(1) regarding the bacterial strains, as related to their availability, has been withdrawn.

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2. Applicants' argue that claim 16 and claims depending on it are definite regarding the phrase "to improve coagulation". They further explain that improving coagulation refers to inducing in milk a greater aptitude to coagulation.

a. The specification does not disclose any criteria for a milk having improved coagulation. Present specification (page 9, lines 18-22) recites "an improvement to be obtained in the aptitude of the milk to coagulate". It is clear that such a statement does not make claim 16 and the dependent claims thereof, definite.

3. Applicants' argue that combination of teachings of '263 (R1) in view of '132 (R2) and '505 (R3) do not make the presently claimed invention obvious.

a. It is agreed that the specific strains as disclosed in the instant application are not used in the processes set forth by R1, R2 and R3. However, incorporation of *Lactobacillus plantarum*, and *Lactococcus lactis ssp. Lactis* are disclosed in cheese making, by the references cited. R1 teaches of using *Lactococcus lactis ssp. lactis* (Col. 4, first paragraph). R2 gives details of lactic acid bacteria including *Lactobacillus plantarum* (see R2, col. 3, detailed description lines 25-40) and their incorporation in cheese (col. 4, lines 43-51, and Col. 5, Table 1). R3 discloses incorporating *Lactococcus lactis ssp. lactis* into raw milk. Therefore the incorporation of these lactic acid bacteria into milk either before the addition of rennet (as disclosed by R1) or addition to raw milk (in storage) as disclosed by R3 or the addition in the form of lyophilized culture as disclosed by R2 is obvious to those of skill in the art.

Furthermore, Claim 16 has been amended to spell out the steps involved in cheese making. All of those steps are disclosed by R1. (please see pending action page 4 paragraph 7)

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4. Applicant has tried to criticize the cited references on their own disregarding the fact that the present claims are being rejected in an obviousness type rejection (35 U.S.C. 103(a).

a. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

However, note that while R2 and R3 do not disclose all the features of the present claimed invention, R2 and R3 are used as teaching reference, and therefore, it is not necessary for this secondary reference to contain all the features of the presently claimed invention, *In re Nievelt*, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973), *In re Keller* 624 F.2d 413, 208 USPQ 871, 881 (CCPA 1981). Rather this reference teaches a certain concept, and in combination with the primary reference, discloses the presently claimed invention.

In the current case, R2 teaches the incorporation of lyophilized lactic acid bacteria and R3 teaches the concept of adding the lactic acid bacteria to the raw milk in storage.

### ***Conclusion***

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period



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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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